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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,617

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Rachel Mary Haywood

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SONNENSCHN NATH & ROSENTHAL LLP

P.O. BOX 061080

WACKER DRIVE STATION, WILLIS TOWER

CHICAGO, IL 60606-1080

EXAMINER

FRAZIER, BARBARA S

ART UNIT

PAPER NUMBER

1611

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,617	<b>Applicant(s)</b> HAYWOOD ET AL.	
	<b>Examiner</b> BARBARA FRAZIER	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12 and 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/6/09 has been entered.

### ***Status of Claims***

2. Claims 1-18 are pending in this application.
3. Claims 9-11, 13, and 14 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/22/08.
4. Claims 1-8, 12, and 15-18 are examined.

### ***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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**6. Claims 1-8, 12, and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jurkiewicz et al ("EPR Detection of Free Radicals in UV-Irradiated Skin: Mouse *Versus* Human", *Photochemistry and Photobiology*, 1996, 64(6): 918-922) in view of Robinson (US Patent 5,968,485).**

The claimed invention is drawn to a method for measuring the effectiveness of a sunscreen composition or other skin preparation in reducing the exposure of human skin to UVA radiation, the method comprising irradiating a sample of human skin or of an effective substitute therefor (herein: "skin"), shielded with the sunscreen composition or other skin preparation to be tested, with UV radiation comprising UVA wavelengths, and determining by electron spin resonance (ESR) spectroscopy the level of induced production of ascorbate radical in the shielded skin; and determining a quantitative measure of the effectiveness of the sunscreen composition in reducing the exposure of human skin to UVA radiation by comparison of the said level of ascorbate radical production in the shielded skin with the level of ascorbate radical production induced in reference skin under substantially quantitatively comparable conditions (see claims 1, 15, and 18).

Jurkiewicz et al. teach EPR (i.e., ESR) detection of ascorbate free radicals in UV-irradiated skin (see abstract). A sample of human skin was irradiated with UV radiation comprising UVA wavelengths, either unshielded or shielded with a shield such as a filter (see page 919, third full paragraph), and the ascorbate radical EPR signal was determined. Jurkiewicz et al. also teach irradiating a sample to which the

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photoprotective agent Desferal has been topically applied, and with which a 305 nm UV cutoff filter was used (page 921, first paragraph).

Jurkiewicz et al. do not teach the use of a photoprotective (i.e., sunscreen) agent in the UVA range (320 - 400 nm), and do not specifically state that a quantitative measure of the effectiveness of the sunscreen composition was determined.

Robinson teaches UVA-absorbing dibenzoylmethane sunscreen actives which absorb UV radiation having a wavelength of from about 320 nm to about 400 nm (col. 3, lines 50-55).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select a sunscreen active in the UVA region (e.g., the sunscreen active taught by Robinson) to be used on the shielded skin. One skilled in the art would have been motivated to do so because the process of Jurkiewicz et al. is taught to be used on unshielded skin in both the UVA and UVB ranges, and because the process is also taught to be used on shielded skin (e.g., when Desferal is topically applied). Therefore, it naturally follows that one skilled in the art would also use the process taught by Jurkiewicz et al. for measuring the effectiveness of a sunscreen active in the UVA region, such as the sunscreen active taught by Robinson.

Regarding the step of determining a quantitative measure of the effectiveness of the sunscreen composition in reducing the exposure of human skin to UVA radiation (claims 1 and 16), it would have been obvious to a person having ordinary skill in the art at the time the invention was made to compare levels of ascorbate radical production in the shielded and reference skin samples. Comparing the data obtained between a

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sample and its comparable reference is generally conventional and well within the capacity of one of ordinary skill in the art (as substantiated by Applicant's remarks on page 14 of the specification), and does not impart patentability to the claims.

Regarding claims 2 and 3, Jurkiewicz et al. teach that the skin sample may be irradiated in the absence of a photoprotective agent (i.e., sunscreen composition or other skin preparation). The steps of measuring a reference using conditions (such as UV radiation and ESR conditions) comparable to those used with the test sample, are conventional steps followed when comparing a test sample to a reference sample, and well within the capacity of one of ordinary skill in the art.

Regarding claims 4 and 5, Jurkiewicz et al are silent with respect to whether or not the test and reference skin samples are the same. However, one skilled in the art of EPR spectroscopy would be able to control the dose of UVA radiation within the parameters of routine experimentation, such that the skin samples could be used once (wherein the test and reference skin samples are different but functionally comparable), or more than once (wherein the test and reference skin sample are the same).

Regarding claims 6 and 7, Jurkiewicz et al teach the UV-induced production of other radicals when the skin samples are irradiated in the presence of a spin trap molecule (page 920).

Regarding claims 8 and 17, the ranges disclosed for UV radiation and UVA radiation are the standard accepted wavelength ranges for UV and UVA radiation, and well within the capacity of one skilled in the art. For example, Robinson teaches that

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the UVA-absorbing sunscreen active absorbs UV radiation having a wavelength of from about 320 nm to about 400 nm (col. 3, lines 52-55).

Regarding claim 12, the method of claim 1 is found obvious for reasons stated above, and the expression of said effectiveness is merely a mathematical manipulation of data obtained by said method, and does not impart patentability to the claim.

### ***Response to Arguments***

7. Applicant's arguments filed 7/6/09 have been fully considered but they are not persuasive.

Applicants argue that Jurkiewicz fails to disclose that there is a quantitative reduction in ascorbate radical signal intensity in proportion with the reduction in radiation exposure and fails to disclose enough information to allow or suggest that ESR spectra from more than one skin sample be compared quantitatively.

This argument is not persuasive because Applicant's claims do not require that the reduction in ascorbate radical signal intensity be in proportion with a reduction in radiation exposure. Additionally, Jurkiewicz et al teach that topical application of Desferal to human skin decreases radical production by about 50% (abstract and page 921), and therefore a quantitative measure (i.e., a reduction of about 50%) is made.

Applicants also argue that the photoprotective action of Desferal is unlikely to be in response to the applied dose (due to its role in reducing generation of free radicals which initiate lipid-peroxidation in membrane lipids, which leads to formation of lipid

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radical intermediates). Applicants argue that, although Jurkiewicz and Buettner did indeed demonstrate a reduction in ascorbate radical signal by Desferal, the relation to the applied concentration was not mentioned, and a reliable quantitative method was not taught.

This argument is not persuasive because Applicant's claims do not require a correlation between the applied dose and the level of induced production of ascorbate radical in the shielded skin, but merely that a "quantitative measure" between the shielded skin and reference skin is made. Since Jurkiewicz et al teach that topical application of Desferal to human skin decreases radical production by about 50% (abstract and page 921), a quantitative measure which compares shielded skin (i.e., skin to which Desferal is topically applied) and reference skin is made. Furthermore, comparing the data obtained between a sample and its comparable reference is generally conventional and well within the capacity of one of ordinary skill in the art, as substantiated by Applicant's remarks on page 14 of the specification. Applicant's specification states that provisions for determining a quantitative measure of the effectiveness of the sunscreen composition or other skin preparation in reducing the exposure of human skin to UVA radiation, by comparison of the levels of ascorbate radical production in the shielded and reference skin samples, will be well within the capacity of one of ordinary skill in this art (see page 14, lines 11-20 of the specification). Therefore, the step of determining a quantitative measure by comparison of shielded and reference skin samples does not impart patentability to the claims.



Applicants argue that the formation of lipid radicals cannot be assumed to be in direct response to the applied irradiation, or a quantitative reduction in proportion to applied heme chelator.

This argument is not persuasive because Applicant's claims do not require that the induced radical production be in direct response to the applied irradiation, but simply that the skin be irradiated, and the level of induced radical production be determined. Even so, Jurkiewicz et al teach that, upon UV radiation exposure, ascorbate as well as spin-trap adduct signals are observed, and the presence of lipid-derived radicals is consistent with previous observations of UV radiation-induced lipid alkyl radicals (see page 920). Additionally, Applicant's claims do not require a reduction in radical formation that is in proportion to applied heme chelator (or other photoprotective agent), but simply that a "quantitative measure" between shielded and reference skin is made. Since Jurkiewicz et al teach that topical application of Desferal to human skin decreases radical production by about 50% (abstract and page 921), a quantitative measure which compares shielded skin (i.e., skin to which Desferal is topically applied) and reference skin is made.

### ***Conclusion***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is

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(571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Sharmila Gollamudi Landau/  
Supervisory Patent Examiner, Art Unit 1611